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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/369,016**

Applicant(s)  
**Farmer**

Examiner  
**Irene Marx**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Mar 6, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 51-59 and 61-68 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-59 and 61-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 3/6/02 has been entered.

Claims 51-59 and 61-68 are being considered on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-54, 61-62-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 is incomplete in lacking a transitional phrase, such as comprising, consisting essentially of or consisting of. Correction is required.

Claim 52 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claims 61-66 are confusing in the recitation "in the form of ...a gel". It is unclear what is intended, inasmuch as claim 67-68, for example, is directed to "a gel". The difference intended cannot be readily ascertained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 56 is/remains rejected under 35 U.S.C. 102(b) as being clearly anticipated by Paul '989. See, e.g., Formulation J, col. 15, lines 10-19, containing a lactic-acid producing bacterium, a fructo-oligosaccharide and sodium gluconate, which is a mineral gluconate.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to Applicant's argument that claim 51 pertains to *B. coagulans*, it is noted that claim 56 pertains to a composition comprising lactic acid producing bacteria and that formulation J contains a lactic-acid producing bacterium, a fructo-oligosaccharide and sodium gluconate, which is a mineral gluconate.

Therefore the rejection is deemed proper and it is adhered to.

Claim 57 is rejected under 35 U.S.C. 102(e) as being anticipated by Reid (U.S. Patent No. 6,004,551). See, e.g., col. 7, lines 57-65 and col. 9, lines 35-45 for the administration to a mammal of a suppository comprising a lactic acid producing bacteria. The effect of increasing bioavailability of nutrients is an inherent property of the composition.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant has correctly identified the reference as U.S. Patent No. 6,004,551. It is now made of record. The argument that Reid is not anticipatory because it does not pertain to *B. coagulans* is noted. However, this argument is not persuasive, since claim 57 is directed to lactic-acid producing bacteria in a suppository.

Therefore the rejection is deemed proper and it is adhered to.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-59 and 61-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hata taken with Paul and Hansen and further taken with Long and ATCC Catalogue of Bacteria.

Hata teach a process of providing a mammal with nutrients by orally administering yogurt composition containing *Bacillus coagulans*. The strain of Hata is also known as *L. thermophilus* (See, e.g., col. 2, lines 28-35). The natural effect of consuming *Bacillus coagulans* containing compositions is to increase bioavailability of nutrients. The reference differs from the claimed invention in that the yogurt does not explicitly contain a fructo-oligosaccharide and gluconate or citrate. However, at least citrate is known to be frequently added to yogurt compositions. In addition, Paul discloses compositions containing lactic acid bacteria and fructo-oligosaccharides, with the indication that fructo-oligosaccharides are a valuable addition to lactic acid producing bacterial compositions because of their contents of soluble fiber, an additive known to be beneficial to general health. In addition the reference teaches the combination of a lactic-acid producing bacterium, a fructo-oligosaccharide and sodium gluconate. (See, e.g., col. 15, lines 10-20). Moreover, Hansen *et al.* disclose the addition of various citrates and gluconates to yogurt, including calcium gluconate and/or calcium citrate for the purpose of adding valuable bioavailable nutrients (See, e.g., col. 4, lines 45) as well as the addition of fibers, which suggests the addition of fructo-oligosaccharides.

The references appear to differ from the claimed invention in that the compositions disclosed do not explicitly recite the presence of lactase. However, Long *et al.* adequately demonstrates that the presence of lactase in *B. coagulans* is inherent in the species. See, e.g., Long *et al.*, col. 4, lines 6-39. Accordingly, one of ordinary skill in the art would have been motivated to administer *B. coagulans* in milk-containing compositions, such as yogurt, with a reasonable expectation of providing compositions which are easily digestible in view of the availability of the lactose degrading enzyme lactase produced by this microorganism.

In addition, ATCC Catalogue adequately demonstrates that *B. coagulans* ATCC 31284, the strains grown by applicants and used in the present invention was previously classified as *Lactobacillus sporogenes* (See, e.g., page 45; Specification, page 16). Therefore, there is a clear nexus between the reference taught compositions and the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose as noted *supra*. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions and ingredients where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition and process of administering nutrients and disclosed by Hata using strains of *Lactobacillus* now reclassified as *B. coagulans* or other *B. coagulans* strains by supplementing the milk-containing composition yogurt, for example, with citrate or gluconate compounds as taught by Paul and Hansen for the expected benefit of increasing the digestibility and the nutritional content of food and thus maximize the health benefits to the mammal being fed.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination

of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references.

Applicant argues that Hata discloses the use of a specific strain of *B. coagulans* having specific nutritional requirements. From this disclosure, applicant appears to conclude that this reference precludes the use of other *B. coagulans* in similar processes. However, applicant's narrow interpretation of the reference is not warranted. Moreover, there is no claim designated limitation to the effect that the claimed composition necessarily must constitute the culture medium for the *B. coagulans* bacteria, as appears to be argued. In addition, there is nothing in the Hata reference that teaches against combining this *B. coagulans* or other *B. coagulans* with the additives taught in the secondary references. Clearly the strain of *B. coagulans* of Hata is suitable for buccal administration, since it is included in yogurt.

Applicants also argue that Hansen does not contemplate making calcium fortified yogurt using *B. coagulans*. However, Hansen is relied upon for the teachings of adding calcium gluconate and/or calcium citrate to any yogurt, regardless of the bacterial source. Therefore, one of ordinary skill in the art would be strongly motivated to add these compounds to any yogurt produced by any microorganism, including, of course, *B. coagulans* for the favorable effects disclosed in the reference and for the recognized need to supply adequate amounts of calcium to humans to prevent osteoporosis, for example. Moreover, that *B. coagulans* is closely related to strains of *Lactobacillus* is adequately demonstrated by the prior classification within this genus of at least two strains, including *B. coagulans* ATCC 31284, the strain disclosed by applicant in the instant specification (See, e.g., Specification, page 16).

As to the argument that Hata administers a mixture of bacteria and the invention does not, the claims as written fail to reflect the feature of administration of the touted "isolated" *B. coagulans*, since at least claim 55 is written in terms of the open language "comprising", such that additional ingredients, including other bacteria, are encompassed even if they are not explicitly recited. If claim 51 intends to read "consisting of", this is not currently of record. Thus, there is no clear correlation between the invention as claimed and the arguments presented.

In any event, it is unclear that the administration of any *B. coagulans* would have the desired effect, in view of the variability of these microorganisms, as evidenced, for example, by encompassing *Lactobacillus sporogenes* and *Lactobacillus thermophilus*, as discussed *supra*.


Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

  
Irene Marx  
Primary Examiner  
Art Unit 1651